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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,869	12/11/2001	Kevin P. Baker	GNE.2830P1C45	9681

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,869	BAKER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-27 and adding new claims 28-47, filed on 11 December 2001 is acknowledged.

Thus claims 28-47 are pending and under consideration.

2. ***Priority:***

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that only the isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:76 (full length) in this application is supported by the disclosure in application serial no. 09/946,374 filed on 04 September 2001. The gene amplification assay on page 494 and table 8 on pages 503, provides a specific and substantial asserted utility for the polynucleotide of SEQ ID NO:76, because the assay shows approximately 2 fold amplification of DNA sequences in lung and colon tumors compared to normal controls, thus providing a specific and substantial asserted utility for the polynucleotide of SEQ ID NO:76. However, neither the isolated nucleic acid encoding the polypeptide of SEQ ID NO:77, nor variants of the nucleic acid of SEQ ID NO:76, are supported by the disclosure in the application serial no. 09/946,374 filed on 04 September 2001, because this prior application does not show that "all possible" nucleic acids encoding the polypeptide of SEQ ID NO:77 or variants of the nucleic acid of SEQ ID NO:76 are also amplified in these tumors.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and

specific page number(s) of any parent application filed prior to 12/11/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 12/11/01.

Information Disclosure Statement:

3a. The information disclosure statements filed 137 November 2003 and 17 September 2003, fail to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because they fail to identify each reference by author and publication date. The references have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 28-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:76, an isolated nucleic acid comprising a nucleotide sequence which completely hybridizes to the nucleotide sequence set forth in SEQ ID NO:76, does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77 or which encodes variants of SEQ ID NO:77. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims 28-47are drawn to nucleic acid encoding the polypeptide of SEQ ID NO:77 or nucleic acid having 80%, 85%, 90%, 95% and 99% to the nucleic acid of SEQ ID NO:76, however, instant specification does not teach how to make or use said nucleic acid. Instant specification discloses a gene amplification assay in Example 143, which demonstrates that PRO1293 (SEQ ID NO:76) DNA was about 2 folds higher in primary lung tumors and in primary colon tumors compared to DNA isolated from normal controls. Therefore, only SEQ ID NO:76 (full length) can be used for diagnostic purposes, because Applicants have not shown that any other nucleic acid or variants, even degenerate variants encoding the same protein was higher in tumor samples as compared to normal samples. Thus, while the nucleic acid comprising the

nucleotide sequence set forth in SEQ ID NO:76, (full length) may be used to detect cancer cells due to increased copy number, the increased copy number of SEQ ID NO:76 does not provide a readily apparent use for all nucleic acids comprising the nucleotide sequences encoding the polypeptide of SEQ ID NO:77, or those that variants of the nucleic acid of SEQ ID NO:76, because there is no information regarding whether degenerate variants encoding the same protein, were increased in cancer tumors compared to normal controls. Furthermore, it is not clear from the specification what types of mutations are allowed in the single, full length probe (i.e SEQ ID NO:76) used in the diagnostic assay without loss of probe specificity, therefore, instant specification does not teach how to use an isolated nucleic acid comprising a nucleotide sequence, which hybridizes less than the full length of SEQ ID NO:76.

The data in the instant specification shows that gene copy number is increased in certain tumor tissue samples, however, it does not necessarily follow that an increase in gene copy number results in increased gene expression and increased protein expression, such that "all possible" nucleic acids encoding the polypeptide of SEQ ID NO:77, or those variants of the nucleic acid of SEQ ID NO:76, would be useful diagnostically or as target for cancer drug development. For example, Pennica et al, (1998, PNAS USA 95:14717-14722) discloses that, "An analysis of WISP-1 gene amplification in human colon tumors showed a correlation between DNA amplification and over expression, whereas, over expression of WISP-3 RNA was seen in the absence of DNA amplification. In contract, WISP-2 DNA was amplified in the colon tumors, but mRNA

expression was significantly reduced in the majority of tumors compared with the expression in normal colonic mucosa from the same patient", see page 14722, second paragraph of column 1; pages 14720-14721. Therefore, the protein levels cannot be accurately predicted from the level of the corresponding gene. Therefore, while instant specification is enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:76, the specification is non enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:77or variants of the nucleic acid of SEQ ID NO:76.

Furthermore, claims 28-32 and 41-47 are drawn to a genus of nucleic acids that are defined only by sequence identity. Due to the large quantity of experimentation necessary to determine all the nucleic acids comprising an nucleotide sequence that is at least 80%, 85%, 90%, 95% or 99% identical to the nucleic acid of SEQ ID NO:76, and to screen for the ones that encode the polypeptide of SEQ ID NO:77, the lack of direction/guidance presented in the specification regarding which variants of the nucleic acid of SEQ ID NO:76 would retain the desired activity, the complex nature of the invention, the absence of working examples directed to variants of the nucleic acid of SEQ ID NO:76, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the unpredictability of the effects of mutation on the structure and function of the claimed polypeptide, and the breadth of the claims which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

4b. Claims 28-32 and 41-47are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims 28-32 are drawn to an isolated nucleic acid that shares "80%, 85%, 90%, 95% or 99%" identity to the nucleic acid of SEQ ID NO:76, and claims 41-47 are drawn to an isolated nucleic acid which hybridize to nucleic acid encoding a specific polypeptide. However, the instant specification only describes the structure of the nucleic acid of SEQ ID NO:76, and therefore, conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written

description of the claimed genus. Vas-cath Inc. v. Mahurkar, 19 USPQ2d I 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." (See Vas-cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2II 1016. Therefore, only the isolated nucleic acid set forth in SEQ ID NO: 76, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 U.S.C. § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 41-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 41 and 42 recite ".... Hybridizes under stringent conditions....", however, this is a conditional term and renders the claims indefinite. This rejection could be obviated by supplying specific conditions supported by the specification, which Applicants consider to be "stringent".

Claims 43-47 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, so long as they depend from claim 41 for the limitations set forth directly above.

Claim Rejections - 35 U.S.C. §102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6a. Claims 28-47 are rejected under U.S.C. § 102 (a) as being anticipated by Baker et al (WO200012708; published on 09 March 2000).

Baker et al disclose an isolated nucleic acid that shares 100% homology to the polypeptide of SEQ ID NO:76 of the instant application. (See attached copies of the comparison of SEQ ID NO:76 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Baker et al also disclose a vector comprising said nucleic acid and a host cell comprising said vector, (see pages 83-85 and claims).

Therefore, since the Baker et al reference meets all the limitations recited in instant claims 28-47, thereby, anticipating the instant claims 28-47 in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
10 June 2004

JANET ANDRES
PATENT EXAMINER